

# EC-Declaration of Conformity

**Manufacturer:**

Name : METKO Medikal ve Tıbbi Cihazlar Dış Ticaret Ltd. Şti.  
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**Authorized European Representative:**

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**Product:** ECG – EKG Cables & Leadwires

**Models:** E100-XXX, E101-XXX, E104-XXX Series EKG Cables, E200-XXX, E201-XXX, E202-XXX, E204-XXX Series, E205-XXX Series, E207-XXX, E208-XXX Series ECG Cables  
E21/XX, E22/XX, E31/XX, E32/XX, E41/XX, E42/XX, E51/XX, E52/XX, E61/XX, E62/XX, E71/XX, E72/XX, E81/XX, E82/XX Series ECG Leadwires  
E-101/XX, E-102/XX, E-103/XX, E-104/XX, E-105/XX Series Diagnostic EKG Leadwires  
HLXX-XX Series ECG Holter Leadwires  
NEI, NEA, NEW, NET Neonatal Prewired Electrodes

**Classification:** Class I Medical Device

We herewith declare that the above mentioned products meet the Essential requirements and conforms to the Medical Device Directive 93/42/EEC.

**Standards:**

EN 60601-1-1: 2001	Medical electrical equipment, Part 1: General requirements for safety
EN 980: 2003	Graphical symbols for use in the labeling of medical devices
EN ISO 9001:2000	Quality management systems-Requirements
EN ISO 13485:2003	Medical devices - Quality management systems -Requirements for regulatory purposes
EN 1041:1998	Information supplied by the manufacturer with medical devices
EN 14971:2000	Medical devices - Application of risk management to medical devices

**Date of issue:** 03.10.2005

**Signature:**



**Name:** Filiz ERSOY

**Position:** Company Manager